Presidential Advisory Council on HIV/AIDS (PACHA)
56th Meeting
Satcher Health Leadership Institute
Morehouse School of Medicine
Atlanta, Georgia
May 22, 2015

Council Members—Present

David Holtgrave, Ph.D., Vice Chair (by phone)
Jeffrey S. Akman, M.D.
Oliver Clyde Allen III
Dawn Averitt
Lucy A. Bradley-Springer, Ph.D., R.N., ACRN, FAAN
Gina M. Brown, M.S.W.
Ulysses W. Burley III, M.D., M.P.H.
Vignetta Charles, Ph.D.
Cecilia C. Chung
William H. Collier (by telephone)
Yvette Flunder, D.Min.
Robert Greenwald, J.D.
Gabriel Maldonado, M.B.A.
Douglas A. Michels, M.B.A.
Michelle Ogle, M.D., FAAP, AAHIVS
Ligia Peralta, M.D., FAAP, FSAHM, AAHIVMS
Mario Pérez, M.P.H.
Harlan H. Pruden
Scott A. Schoettes, J.D.
Vanessa D. Sharp, M.Div., MACM, MATM
Elizabeth Styffe, M.S.N. (by telephone)
Mildred Williamson, Ph.D., M.S.W.

Council Members—Absent

Ada A. Adimora, M.D., M.P.H.
Humberto Cruz, M.S.
Patricia Garcia, M.D., M.P.H.
Grissel Granados, M.S.W.
Nancy Mahon, J.D., PACHA Chair
Lawrence A. Stallworth II

Staff

Kaye Hayes, M.P.A., PACHA Executive Director
Caroline Talev, M.P.A., Public Health Analyst
Chynna Cole, B.B.A., ORISE Fellow

Federal Liaisons

Eva Margolies, M.P.A., Associate Director for Planning and Policy Coordination, National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention, Centers for Disease Control and Prevention (CDC)
Ronald O. Valdiserri, M.D., M.P.H., Deputy Assistant Secretary for Health, Infectious Diseases; Office of HIV/AIDS and Infectious Disease Policy, Office of the Assistant Secretary for Health, U. S. Department of Health and Human Services (HHS)
John Ward, M.D., Director, Division of Viral Hepatitis, National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention, CDC

Presenters

Ryan Clary, Executive Director, National Viral Hepatitis Roundtable
Gregg Gonsalves, Ph.D., Co-Director, Yale Global Health Justice Partnership, Yale Law School and Yale School of Public Health
Camilla Graham, M.D., M.P.H., Co-Director, Viral Hepatitis Center, Division of Infectious Diseases, Beth Israel Hospital
Shannon Hader, M.D., M.P.H., Director, Division of Global HIV/AIDS, CDC
Benjamin Linas, M.D., Director, HIV Epidemiology and Outcomes Research Unit, Boston University School of Medicine

Welcome

Kaye Hayes, M.P.A., PACHA Executive Director, called the meeting to order at 9:05 a.m. and welcomed the members of the Council and meeting attendees. (PACHA Chair Nancy Mahon, J.D., was unable to attend.) Ms. Hayes outlined the agenda. She thanked the PACHA staff, Caroline Talev and Chynna Cole, for their hard work; Ronald O. Valdiserri, M.D., M.P.H., for his support and leadership; and David Satcher, M.D., Ph.D., director of the Satcher Health Leadership Institute, for providing the meeting facilities.

Roll Call

Ms. Hayes called the roll.

Hepatitis C and Barriers to Treatment

Moderator: Robert Greenwald, J.D., PACHA Member

Thanks to new treatments for hepatitis C virus (HCV), elimination of HCV is a reality, said Mr. Greenwald. However, restrictions to access to care for HCV are severe and unlike anything seen with HIV, mostly related to the cost of the treatment, he noted. HCV is the number one killer of coinfected people living with HIV/AIDS (PLWHA).

Mr. Greenwald circulated a draft letter to HHS Secretary Sylvia Mathews Burwell making the case that current restrictions to HCV treatment are discriminatory and unreasonable. Proposed recommendations include the following:

- Direct the Centers for Medicare & Medicaid Services to provide guidance to Medicaid programs on evidence-based, nondiscriminatory treatment criteria
- Amend the Essential Health Benefits rule to require HCV treatment coverage and prohibit excessive coinsurance rates
- Require plans to provide complete, accurate formulary information that includes out-of-pocket costs
- Ensure prompt investigation of complaints about discriminatory practices.

Mr. Greenwald urged PACHA members to provide input and finalize the draft as quickly as possible. Douglas A. Michels, M.B.A., requested the addition of language on screening for HCV; Mr. Greenwald agreed, because the need to identify those infected and link them to care remains, regardless of the individual's access to new drugs.

Lost Opportunities in Hepatitis C Care

Camilla Graham, M.D., M.P.H., Co-Director, Viral Hepatitis Center, Division of Infectious Diseases, Beth Israel Hospital

Dr. Graham said "hysteria" related to the cost of new HCV drugs resulted in lost opportunities to improve medical care, such as opportunities to identify HCV-infected patients before they develop severe complications. In 2013, the U.S. Preventive Services Task Force recommended screening for HCV for those born between 1945 and 1965. (Such screening is not subject to cost-sharing under the Affordable Care Act [ACA].) The subsequent increase in screening was met with resistance from primary care providers, who felt overwhelmed and were concerned about creating panic if infected patients could not gain access to the new drugs. However, without screening, people with HCV will not receive other treatments or counseling to maintain their health, said Dr. Graham. About 25 percent of baby boomers already have cirrhosis, she noted.

Medical restrictions imposed by payers limit coverage of curative drugs to those with late-stage complications of HCV, usually cirrhosis. Patients treated early can be cured, and their risk returns to that of those who never had HCV. Those treated in later stages also are cured but remain at high risk for hepatocellular carcinoma, which requires screening every 6 months.

Some plans require a patient to demonstrate up to 12 months of sobriety before HCV treatment is covered. The U.S. Department of Veterans Affairs (VA) guidelines specifically state that no published data support such a criterion.

Capacity also poses a barrier. Dr. Graham pointed to an assessment that found that 7,000 beneficiaries of MassHealth (the Massachusetts Medicaid program) have been diagnosed with HCV. More than 90 percent have been approved for treatment, but only 14 percent have received treatment. Despite MassHealth's generous coverage of HCV with few restrictions and a high provider-to-patient ratio, it faces real problems related to capacity.

Mr. Greenwald said the small percentage of people treated also may be related to the fact that consumers only hear about the high costs of the drugs and the restrictions to access. Dr. Valdiserri reminded the group about the importance of health literacy and consumer awareness in treating HCV.

The opportunity to frame the cure for HCV as a key step in prevention of the spread of HCV also has been overlooked, said Dr. Graham. Similarly, the integration of HCV treatment with addiction medicine programs has not been addressed.

The Cost and Cost-Effectiveness of New Therapies to Treat HCV

Benjamin Linas, M.D., Director, HIV Epidemiology and Outcomes Research Unit, Boston University School of Medicine

Dr. Linas stressed that the goal of cost-effectiveness research is not to find ways to save funds but rather to maximize and improve public health given finite resources. He also said cost-effectiveness is not the same as cost savings (as very few medical treatments save funds), nor is it equivalent to affordability in the short term, because cost-effectiveness requires a long-term, societal perspective.

Effectiveness is usually measured in terms of quality-adjusted life years (QALY), and improvements in cost-effectiveness are usually incremental. To assess cost-effectiveness, one must ask what society is willing to pay. To answer that uncomfortable question, researchers look at other expenses paid routinely and how they break down in terms of cost per QALY. For example, HIV antiretroviral therapy costs about $31,500 per QALY, while dialysis for advanced disease costs about $187,000 per QALY.

Studies published in early 2015 demonstrate that the cost-effectiveness of HCV therapies is under the commonly accepted threshold of $100,000 per QALY, and often less than $50,000 per QALY. New HCV drugs are therefore already closer in cost-effectiveness to widely accepted treatments for other conditions.

Concerns have been raised about the affordability of HCV treatment given the prevalence of the disease. As many as 4 million people may be HCV-infected, and nearly half of them are covered by Medicaid or Medicare. Treating all of them would cost $140 billion over the next few years. However, Dr. Linas pointed out, not all of them will actually seek care, and certainly not in the next 5 years, so the concern may be an overreaction.

More importantly, said Dr. Linas, the actual cost of treatment is not known. Payers negotiate with drug companies, and no one pays the list price. Because these negotiated prices are confidential and specific to each payer, the real costs are difficult to evaluate. Poor information leads to poor policy, Dr. Linas concluded.

Mr. Greenwald pointed out that curative treatments for other diseases are on the horizon, so it is important to set a strong precedent for the role of cost-effectiveness in decisionmaking. He proposed adding a call for transparency in drug pricing to the PACHA letter in development.

The Hepatitis C Treatment Action Crisis

Ryan Clary, Executive Director, National Viral Hepatitis Roundtable

Mr. Clary said the arrival of a cure should have been met with bold action and planning, yet access remains restricted. He described a host of barriers advocates have faced in their efforts to ensure access to HCV treatment for all:

- Providers have been reluctant to screen for HCV because they feel they cannot promise access to treatment.
- A massive public relations campaign, led by payers, focused on the cost of the treatment—$1,000 per pill. Media coverage of the cost has been extensive, and reporters continue to cite the list price rather than the real costs of treatment.
- The immediate treatment crisis has been overlooked, even as advocates take on the larger questions of drug pricing and access.
- Misinformation abounds, such as the concept that providing access would cost governments $140 billion right now.
- Stigma related to the association of HCV with injected drugs has played a role and sparked discussion about who is "worth treating."
- Payers have dismissed treatment guidelines developed by experts.
- Few people with HCV are part of the policy conversations about price and access, and their voices have been drowned out.

Mr. Clary pointed out that while prices are still too high, market competition has lowered prices, and payer negotiations have expanded access. Advocacy also has helped drive access to care. A growing movement has made the case for the cost-effectiveness of HCV treatment and highlighted the wide variations in costs across States.

Early access to treatment is vital, yet payers continue to place restrictions on who can be treated and when so they can avoid paying for the drugs, said Mr. Clary. Even in MassHealth, managed care beneficiaries face severe restrictions that their counterparts in the fee-for-service plans do not.

Mr. Clary called for reframing the message. While cost is a concern, especially for Medicaid programs, advocates should focus on 1) transparency, so that actual cost data are collected; and 2) accurate information, so that barriers to care are based on scientific evidence. Treatment denials undermine the intent of the ACA, and lawsuits underway may bring that fact to light.

As with HIV, treatment of HCV is important not just for individuals (who benefit regardless of their life stage or disease stage), but also for communities and for the health care system, which has an opportunity to eradicate a chronic infectious disease. Moreover, other cures are coming, as Mr. Greenwald noted, so it is important to determine how society will negotiate access to new care options. Finally, like HIV, access to HCV treatment is a matter of social justice, as those most affected are African

Americans, Native Americans, Latinos, current and former injection drug users, and those who have been incarcerated.

Tackling HCV Drug Prices

Gregg Gonsalves, Ph.D., Co-Director, Yale Global Health Justice Partnership, Yale Law School and Yale School of Public Health

Dr. Gonsalves stressed that immediate steps to determine a fair price for HCV drugs rely on two key components: 1) enhancing the collective bargaining power of State Medicaid programs and other State institutions and 2) ensuring transparency in pricing. He called for an annual *Consumer Reports*-style assessment of what every State Medicaid program pays for HCV drugs, as well as prices paid by other State institutions, such as prison systems.

Dr. Gonsalves emphasized that State prison systems pay close to the list price for drugs, unlike Federal prisons, which negotiate significant discounts. State prison facilities negotiate with payers individually.

Another, longer-term approach to bringing drug costs down is development of generic equivalents. The availability of generic HIV drugs dramatically reduced prices and expanded access to HIV drugs in Africa and elsewhere. The generic drug manufacturer quickly recouped its investment in the enterprise.

Section 1498 of the U.S. Code allows the Federal Government to override patent protection for public use purposes, and the Department of Defense has exercised this power, said Dr. Gonsalves. Alternatively, the Federal Government can seek to buy out a patent (with the patent-holder's consent) and place it in the public domain. However, these options represent a radical new approach beyond the comfort level of most policymakers. PACHA's support for transparency and collective bargaining can help, Dr. Gonsalves concluded.

Discussion

PACHA members raised numerous issues. For example, barriers to testing for HCV persist, such as requirements for transient elastography (FibroScan), which may not be covered by payers; genotyping; and assessment of viral load. Dr. Graham said some health care providers have succeeded in eliminating the FibroScan requirement by demonstrating that it is unnecessary.

Surveillance data on reinfection following treatment are limited. Lack of access to substance abuse treatment poses concerns about reinfection. More investment should be made in HCV treatment research, including surveillance and understanding the public health implications of HCV treatment, to support ethical and evidence-based decisionmaking.

Previous efforts to allow collective bargaining to reduce costs for AIDS drug assistance programs failed, even though bargaining could have saved the Federal Government billions of dollars. Successful negotiation efforts could have the unintended consequence of creating silos of care with limited access. Dr. Gonsalves pointed out that transparent pricing would improve States' ability to negotiate. States could demand that prices negotiated for their Medicaid programs also apply to other State institutions.

Dr. Linas stressed that it is absurd and destructive to craft policies based on inflated list prices. He believes that Medicaid programs pay $30,000–$40,000 for a course of HCV treatment. Other drugs are in development, but they are unlikely to bring prices down.

Other points raised during discussion include the following:

- Treatment of HCV is complex. It requires as much or more follow-up than HIV treatment and is often further complicated by comorbidities.
- Medical judgment and evidence must play a role in policymaking, so that arbitrary restrictions on treatment are eliminated.
- Strong Federal regulations on payer practices are needed. (A new proposed rule aims to eliminate discriminatory drug policies related to HIV treatment.)
- Community awareness about HCV screening and treatment is very low. Advocacy organizations should build coalitions to get the word out.

Mr. Greenwald clarified that the draft recommendations include steps the Administration can take on its own. Some steps may require Congressional legislation. PACHA's role is to advise and make recommendations; it is up to the Administration to determine how (and whether) to enact the recommendations. Mr. Michels strongly encouraged PACHA to engage in dialogue with the entire industry—pharmaceutical manufacturers, payers, and insurers—about possible solutions.

PACHA members agreed that the draft letter should be revised to address the following:

- A continued need for screening and treatment referral
- Unnecessary restrictions, FibroScan in particular, and noninvasive blood tests
- Transparency in drug pricing and price negotiations, specifically a recommendation for an annual Federal report that lists the prices paid for new HCV drugs by all State Medicaid programs and other State programs (e.g., departments of corrections) and by key Federal programs, such as Medicare, VA, and the Bureau of Prisons
- Transparency in research and development costs to illuminate the cost of getting a drug to market
- Strong links between HCV and HIV
- A need for dramatically increased surveillance and communication of the results in a highly visible manner (similar to AIDSVu)

- A need to raise awareness about the waiting list for HCV treatment
- The opportunity to demonstrate decreases in HCV infections where treatment is available
- The use of technology (e.g., risk predictors) to enhance screening
- A residual risk of liver cancer when treatment is delayed until the advanced stages of the disease.

David Holtgrave, Ph.D., moved to approve the draft letter with amendments as discussed, authorizing Mr. Greenwald to use his judgment in incorporating the additional text sent by members and to finalize the draft within 10 days. Jeffrey S. Akman, M.D., seconded the motion. The process for review by PACHA was discussed. Mr. Michels and Lucy A. Bradley-Springer, Ph.D., R.N., ACRN, FAAN, requested e-mail review before approval, but Ms. Hayes clarified that PACHA must vote in a public meeting to accept or reject the document. The majority of PACHA members voted in favor of the motion, with one opposed (Mr. Michels) and two abstaining (William H. Collier and Gabriel Maldonado), and the motion passed.

> **Motion Approved:** PACHA endorses the letter to Secretary Burwell offering a rationale and recommendations for improving access to new HCV medical treatment. (See https://www.aids.gov/federal-resources/pacha/meetings/2015/hcv-letter-from-nancy-mahon.pdf.)

National HIV/AIDS Strategy (NHAS) Discussion and Next Steps

Mario Pérez, M.P.H., PACHA member

Mr. Pérez presented a draft document compiled by all the PACHA Subcommittee Chairs summarizing recommendations for the next iteration of the NHAS. To avoid redundancy, the document is organized around five themes:

- Access to health systems and system responsiveness
- Timeliness, completeness, and robustness of tools to measure NHAS progress
- Disparities and social determinants of health
- HIV criminalization
- HIV comorbidities.

A final section, "Additional Considerations," addresses lessons learned from global efforts and significant changes in health care financing since the NHAS was published. Mr. Pérez said that while there is ongoing debate on the matter, he feels that the ACA has not been fully implemented, and references to full implementation should be removed from the draft. He added that PACHA has not had enough time to make specific recommendations that are measurable, as Douglas Brooks, director of the White House Office of National AIDS Policy, requested.

Discussion

Dr. Holtgrave added that the draft represents areas of common agreement across the PACHA Subcommittees, but it does not include everything PACHA members would like the next iteration of the NHAS to say. PACHA members are encouraged to submit additional comments to the White House as invited by Mr. Brooks. Mr. Greenwald suggested that the PACHA Subcommittees submit comments independent of PACHA.

Dr. Akman pointed out that the document focuses on viral suppression but not on biomedical research toward a cure for HIV. Mr. Pérez said PACHA will have an in-depth discussion about viral suppression at its fall 2015 meeting.

PACHA members agreed that the draft document should be revised to include the following:

- Access to reproductive health care and family planning
- Viral suppression and functional cure
- Universal testing for HIV (including lessons learned from universal screening of pregnant women)
- Laws and statutes (other than HIV criminalization) that fuel disparities and delay access to care
- "Critical enablers" defined by the World Health Organization in its HIV prevention and treatment guidelines
- Role of Tribal entities and the needs of Native Americans
- Comprehensive sex education.

Dr. Holtgrave said that lessons learned from the global response to HIV will be addressed in depth at the fall 2015 PACHA meeting. The PACHA Global Subcommittee may submit additional comments to the White House for the NHAS.

Mr. Greenwald moved to approve the draft document with amendments as discussed, authorizing Mr. Pérez to use his judgment in incorporating the additional text sent by members and to finalize the draft for submission to the White House by May 27. Ligia Peralta, M.D., FAAP, FSAHM, AAHIVMS, seconded the motion. PACHA members voted unanimously in favor of the motion.

> **Motion Approved:** PACHA endorses the recommendations to the White House for the next iteration of the NHAS. (See https://www.aids.gov/federal-resources/pacha/meetings/2015/pacha-updated-nhas-ecommendations.pdf.)

Recognition of Retiring Members

Ms. Hayes said Dawn Averitt, Humberto Cruz, M.S., and Patricia Garcia, M.D., M.P.H., have completed their terms as PACHA members. She thanked them for their work to support PACHA and its goals.

Global Update

Shannon Hader, M.D., M.P.H., Director, Division of Global HIV/AIDS, CDC

Dr. Hader explained that despite tremendous progress toward preventing and treating HIV/AIDS around the world in the past 10 years, the need for services is growing, because the rate of infections is outpacing deaths from HIV/AIDS. Currently, there is a window of opportunity for accelerating effective approaches that could decrease the overall burden of HIV/AIDS, but that opportunity requires some investment.

The Joint United Nations Programme on HIV/AIDS advocates for acceleration. It established the "90-90-90" goal for mitigating ongoing transmission: 90 PLWHA know their status, 90 percent of those in care are receiving effective treatment, and 90 percent of those in care have achieved viral suppression.

Given the flat budget for the President's Emergency Plan for AIDS Relief (PEPFAR) and other global response funds, Dr. Hader said, the global HIV/AIDS community must ask itself which of its activities will have the greatest impact and must prioritize those efforts. The U.S. Department of State and PEPFAR are leading countries in the process of analyzing data to identify their largest gaps and focus on efforts with the greatest potential impact.

Nearly 40 countries are required to submit to PEPFAR an operating plan that 1) incorporates survey data, program service information, expenditure analysis, and other data and 2) maps those data to identify, for example, HIV/AIDS prevalence, incidence, burden of disease, sites of care, and volume at those sites to determine how to provide services equitable to the epidemic (rather than even distribution of services across the country). Country leaders will then meet with PEPFAR and CDC staff for a week-long intensive review and revision of the plan.

As a result of this process, the Dominican Republic determined that by providing more intense services in fewer provinces to men who have sex with men (MSM) and female sex workers, it could successfully link three times more MSM and female sex workers to services. Similarly, Ghana concluded that by decreasing the number of service sites and focusing on providing treatment services to key populations in the areas of highest need, it could link more PLWHA to care and retain them in care. These efforts require prioritization, Dr. Hader stressed. Every country is different, she added, so talking through the plans in depth is a valuable process.

Dr. Hader summarized some of the lessons learned by CDC, which generates data and helps countries create systems for generating and analyzing evidence to support decisionmaking. Such lessons include the following:

- The availability of more granular-level data helps users look more closely at the impact of services.
- Coordinating data provides new insights.
- Data are never perfect or self-explanatory. Discussion is needed to interpret the data for decisionmaking.
- Expenditure analysis drives countries to assess the reasons behind high costs and to evaluate whether the services are being provided in the right way, to the right populations, and in the right places. Such analysis can help decisionmakers understand tradeoffs and opportunities for improvement.

Dr. Hader concluded that the current system for analyzing services reveals which people a program reaches. A fundamental goal of team data analysis is to identify who is missed because there are not enough services or the right kind of services. The effort shifts focus from the known to the unknown, she concluded.

Discussion

Dr. Hader said the biggest challenge of the intensive review of country operating plans is that despite extensive data collection, customized data tools, and expert insight, there is no clear, "right" answer to how to proceed. The ambiguity feeds indecision, she said.

Asked to articulate lessons learned from the Ebola virus outbreak and response, Dr. Hader said the epidemic confirmed that good support and high-quality services are key to building trust in communities. Reluctance to seek treatment highlighted the human aspects of good medicine and good health and the importance of cultivating trust over time, she said.

Adjournment

Dr. Holtgrave thanked the PACHA staff, the members, and participants. He adjourned the meeting at 12:30 p.m.